

REMARKS

This is in response to the Office Action mailed July 16, 2008. Applicants have amended the claims, without prejudice or disclaimer, canceling claims 1-2 and 13-16 and amending claims 3-8, 10-12 and 17-26. Accordingly, claims 3-12 and 17-32 are pending for examination. Support for the amendments to the claims is found throughout specification. Support in the specification for the amendments to claim 3 in Ar¹ can be found, for example, on page 48, second paragraph. Support in the specification for the amendments to claim 3 in Ar² can be found, for example, on page 48, first paragraph. Support in the specification for the amendments to claim 3 of E, G, M, Q and U can be found, for example, on page 43-44. Support in the specification for the amendments to claim 3 in R⁶ and R⁷ can be found, for example, on page 68, first and second paragraphs. Support in the specification for the amendments to claim 3 in R⁸, R⁹ and R¹⁰ can be found, for example, in the descriptions of these radicals in the specification. No new matter has been added.

Election/Restrictions

On page 3 of the Office Action, the Examiner has stated that the following has been treated as the elected subject matter by the Examiner:

A is (optionally substituted by non-heterocyclic groups) aryl, D is NHCYNHCH₂, Y is O or S and B is phenyl substituted by O- (optionally substituted by non-heterocyclic groups) pyridine as set forth in claim 1.

On page 8 of the Office Action, the Examiner has stated that claims 1 and 2-5 and 10 would be deemed allowable if rewritten to this elected subject matter. Applicants respectfully submit that claim 3 as amended conforms with a reasonable number of species in addition to those species treated by the Examiner as elected subject matter. The remaining non-withdrawn claims depend directly or indirectly from claim 3. Applicants note that the cancellation of claims 1 and 2 and the

amendments made to claims 3, 4 and 6 are not for reasons of patentability but are made in order to comply with the election of species requirements that govern examination practice.

Furthermore, the Examiner has withdrawn claims 6-9 and 11-32 from consideration as directed to non-elected subject matter. Applicants respectfully request that claims 6-9 and 11 be considered by the Examiner as these claims have unity of invention with claim 3 from which they directly or indirectly depend. Regarding withdrawn claims 12-32, claims 12 and 17-30 are directed to method claims which directly or indirectly depend from claim 3. Accordingly, applicants request that upon allowance of the claim 3 that these claims be rejoined as permitted under the MPEP guidelines. Regarding the Examiner's prior rejection of "use" claims, applicants have either cancelled the use claims or have amended the claims to be in method claim format.

Written Description/Enablement Rejections

The Examiner has rejected claims 1-5 as lacking adequate written description and non-enabled with respect to the recitation of "derivatives" and "solvates." Without acquiescing in the Examiner's grounds for rejecting the term "derivatives," applicants have obviated this rejection by deleting this term. The Examiner's rejection of the term "solvates" is respectfully traversed below.

The Examiner has objected to the term "substituted" in claim 1. This rejection has been obviated because claim 1 has been cancelled for election of species reasons as discussed above.

Applicants respectfully traverse the rejection of the term "solvates" as follows. Applicants attach hereto three scientific articles showing that there are numerous and routine methods of detecting, isolating and characterizing solvates of pharmaceutical compounds, including detection and isolation by infrared FT-Raman spectroscopy and production by crystallization, spray drying and/or freeze drying. Moreover, as discussed in on page 951 of the attached Byrn et al. reference, hydrates (one of the

most common forms of solvates) can be produced by methods as routine as wet grinding. The attached references are:

- 1.) Byrn et al.; Pharmaceutical Research; Pharmaceutical Solids: A Strategic Approach to Regulatory Considerations; Vol. 12; pps 945-954; 1995
- 2.) Yu et al.; Journal of Pharmaceutical Sciences; Existence of a Mannitol Hydrate during Freeze-Drying and Practical Implications; Vol. 88; pps 196-198; February 1999
- 3.) Otsuka et al.; Pharmaceutical Research; Physicochemical Stability of Phenobarbital Polymorphs at Various Levels of Humidity and Temperature; Vol. 10; pps 577-582; 1993

Accordingly, applicants submit that methods for making and using the claimed solvates would not require undue experimentation. Also, applicants respectfully submit that the claims do not specify any specific solvate forms and are generic to any solvate and therefore a description of specific solvate structures in the specification is not required to comply with the written description requirement. Applicants therefore respectfully request reconsideration and withdrawal of the written description and enablement rejections directed to the term "solvates" in the rejected claims.

Indefiniteness Rejections

The Examiner has rejected claims 1-5 and 10 as indefinite. The Examiner has rejected the use of the plural in the terms "derivatives, salts and solvates." Applicants respectfully traverse this rejection. The rejection of "derivates" is rendered moot by the deletion of this term from the rejected claims. With respect to "salts" and "solvates," applicants submit that using the plural form does not render the rejected claims unclear. Although as the examiner correctly points out, the plural form would include mixtures of salts and/or solvates, this does not render the claims unclear. Applicants respectfully submit that the rejected claims would not confuse the skilled artisan because they include within their scope two or more pharmaceutically acceptable salts or solvates.

Furthermore, the examiner has rejected claim 10 as indefinite on the grounds that the claims fails to recite an inert carrier. Applicants respectfully traverse this rejection.

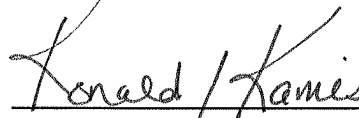
Claim 10, as amended, recites "the compound of claim 3 in a pharmaceutical composition." The term "pharmaceutical composition" is a term that is well known in the art and is further described in the specification and for example, by depending claim 11. Accordingly, applicants respectfully request reconsideration and withdrawal of this rejection or alternatively if the rejection is maintained, applicants respectfully request that the Examiner state why claim 10 would be considered unclear to the skilled artisan.

Conclusion

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below to expedite prosecution.

Respectfully submitted,

By



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